



# FDA's Role in the Silicone Breast Implant Story

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**FDA's Role in the Silicone Breast Implant Story**

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## **I. Introduction**

Silicone breast implants have been the subject of much debate. The product entered on the market without having been adequately tested, and in the late 1980s, pressure mounted on the Federal Food and Drug Agency (FDA) to ascertain the risks associated with these implants or remove them from the market. In April 1992, FDA decided that the information available was insufficient to establish the safety of silicone breast implants, and access was restricted to women participating in clinical trials. Although some hailed the decision as a necessary protective measure, many commentators have criticized the agency's final choice, as well as the decision-making process that preceded it.

This paper will present the history of FDA's policy regarding silicone breast implants, as well as an analysis of the strengths and weaknesses of these actions. Although FDA Commissioner David Kessler's essential judgment that the implants had not been proven safe was sound, both in evaluating the nature and quality of the scientific evidence available, and in adhering to the Congressional guidelines for the type of proof necessary before a device can be approved for marketing, there were many flaws along the way.

In terms of FDA's internal procedures, the breast implant case has demonstrated that more rigorous standards should be set for the data that is reviewed in determining a product's safety and effectiveness, and in selecting the advisory panels that will evaluate this data. In addition, the public confusion and concern that arose regarding the dangers of implants highlight the necessity for a carefully considered public information strategy to better manage the messages conveyed to the public, particularly through mass media outlets.

The decision to distinguish between women seeking breast implants for augmentation and those desiring reconstructive surgery after mastectomies may prove to have been a unique policy

dilemma for FDA, in that most choices will not involve the assessment of psychological benefits of a product in determining if approval is warranted. Nevertheless, the controversy that was stirred exemplifies the dilemma FDA faces in setting policies that are not overly restrictive of individual autonomy yet sufficiently protective of public health.

## **II. Background on Breast Implants**

In 1962, Dow Corning introduced the first silicone gel breast implants, consisting of a rubbery silicone envelope containing silicone gel. These devices were viewed as a great improvement over the direct silicone injections that had been used from the 1940s until that time, and that had caused painful and disfiguring side effects when scar tissue developed around the silicone globules. Certain side effects became apparent almost from the outset, and both Dow and the other manufacturers that later joined the market competed to improve the devices. The saline-filled implant was a significant innovation designed to combat the problem of gel leakage. This product was thought to be safer, because any leakage would be of harmless saline. There are drawbacks with this type of implant as well, however. The consistency of saline implants is not as natural as that of those filled with silicone gel, and if the implants are not filled correctly they can be too hard or can crumple and cause wrinkles in the skin around them. In addition, they can spontaneously empty. For these reasons, before FDA's 1992 action removing silicone implants from the market, 97 percent of women who had implants chose those filled with silicone gel. At this point, by default, saline-filled implants are the type most commonly used, but a new version is being developed that uses soybean oil as the filling substance.

The early customers for breast implants were mostly actresses and showgirls, but over time, more women viewed implants as a method of enhancing self-esteem. In addition, the early users sought unnaturally large implants to please male audiences, but as augmentation became more widespread, most women merely wanted to feel more normal rather than to be conspicuous. The pattern of implant use seen in a midwestern community indicates that in 1991, the average

MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 38-44 (1996).

age of implant recipients was 36, and approximately 85 percent of the women receiving implants were married. This pattern is probably fairly representative of the rest of the country, although implant use is more popular in some regions of the country than others.<sup>2</sup>

Silicone gel breast implants present various risks for women receiving them, both short-term and long-term, local and systemic. As with any implanted device, a risk of local infection exists. Additionally, there are risks that the capsule will rupture, releasing the silicone and reducing the effectiveness of the device. The incidence of this problem is unknown<sup>3</sup>, and measuring its prevalence is complicated by the phenomenon known as silent rupture, when women are unaware that their implants have ruptured until the leakage is detected through a mammogram or the woman specifically investigates the condition of her implants with her physician.<sup>4</sup> The syndrome of gel bleed presents another localized risk. Molecules of the silicone gel migrate through the pores in the surrounding envelope, and tiny particles can escape into the nearby lymph glands.<sup>5</sup> Another side effect is capsular contracture, a contraction of scar tissue that squeezes the implant, making it hard and unnaturally rounded. The contracture produces visible bulges in the breast and can cause painful hardening.<sup>6</sup> It is estimated that to some extent, this occurs for one-third to one-half of silicone implants.<sup>7</sup>

<sup>2</sup> *Id.* at 46-47.

<sup>3</sup>

As of 1995, the studies suggested a rate between 5 and 51%, and scientists were unable to

determine with any confidence where within that enormous range the actual rate lies. *Hearings on Silicone Implants Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Reform and Oversight*, 100 Cong., 2d Sess. 100 (1987) (statement of David A. Kessler, M.D., Commissioner, FDA, and D. Bruce Burlington, M.D., Dir., Center for Devices and Radiological Health). [hereinafter Kessler statement].

Kessler statement, *supra* note 3.

<sup>5</sup>

ANGELL, *supra* note 1, at 41.

<sup>6</sup> *Id.* at 40.

HOUSE COMM. ON GOVT. OPERATIONS, **HR. REP.** No. 101-1006, 101st Cong., 2d Sess (1990), *available in* WESTLAW, 1991 WL 10980 (Leg. Hist.).

The long-term systemic effects of implants are still uncertain. At one time, researchers suspected that implants increased the risk of breast cancer, yet the evidence available in 1995 indicates that no increased incidence of breast cancer or any other type of cancer is associated with silicone gel implants. Two major epidemiological studies that were ongoing for 10 years by 1995 provide definitive data that breast implants does not induce an increased risk of breast cancer. In certain cases, silicone implants may interfere with the accuracy of mammography, and further research is needed to assess whether specialized techniques can obviate this problem.<sup>8</sup>

The risk that has received the most attention and caused the most controversy is that of autoimmune disorders, grouped generally as connective tissue diseases. These diseases include very rare illnesses, such as scleroderma and lupus, and relatively more common conditions such as rheumatoid arthritis, and fibromyalgia.<sup>9</sup> These disorders involve a disturbance in the immune

system that produces an autoimmune response. A civil war within the body ensues, producing io extreme weakness and fatigue, and causing damage to the joints, skin, and internal organs.

<sup>8</sup> *Silicone gel breast implants*, JAMA 2602, Dec. 1, 1993, 1993 WL 12281182 [hereinafter JAMA].

Kessler statement, *supra* note 3.

<sup>10</sup>

ANGELL, *supra* note I, at 21.

### III. History of FDA Actions

#### A. 1976 Amendments

Under the Federal Food, Drug, and Cosmetic Act as passed in 1938, FDA had limited authority to regulate medical devices. The agency could only act against products deemed adulterated<sup>12</sup> or misbranded<sup>13</sup>, and only after such devices were introduced into interstate commerce. The only enforcement remedies available were seizure, injunction, and recommending criminal prosecution. With the devices on the market at that time, this mechanism was appropriate. Most devices were simple so professionals could recognize defects. Thus, the main concern of FDA was assuring truthful labeling and removing grossly hazardous products from the stream of commerce. <sup>i4</sup>

The post-World War II era bio-medical revolution brought a wide variety of sophisticated medical devices into use, such as the pacemaker, kidney dialysis machine, defibrillators, cardiac and renal catheters, surgical implants, artificial vessels and heart valves, intensive care monitoring units, and other diagnostic and therapeutic devices. At times, these devices were introduced without adequate premarket clinical testing, quality control in the materials selected, or patient

21 U.S.C. § 301 et seq.

<sup>12</sup> Adulterated is defined as containing a filthy, putrid, or decomposed substance, or having been

prepared, packed or held under insanitary conditions. 21 U.S.C. § 351 (a)(1).

<sup>i3</sup> A product is misbranded if it bears labeling that is false or misleading; that fails to identify the

manufacturer, packer, or distributor and quantity of contents; that does not incorporate the required labeling statements prominently; that fails to bear adequate directions for use or adequate warnings; or if the product is dangerous to the health when used as indicated. 21 U.S.C. § 352.

~ COMM. ON INTERSTATE AND FOREIGN COM., REPORT ON MEDICAL DEVICE

AMENDMENTS OF 1976, HR. REP. No. 94-853, 94th Cong., 2nd Sess., at 6 (1976), *reprinted in* FOOD AND DRUG LAW INSTITUTE, AN ANALYTICAL LEGISLATIVE HISTORY OF THE MEDICAL DEVICE AMENDMENTS OF 1976, app. III (1976).



consent. Thus, although these items were legitimate medical devices, they did present hazards to public safety, and in the early 1960s, FDA began to focus on these dangers. <sup>15</sup>

With the expansion of the agency's authority over drug regulation accomplished by the 1962 amendments, FDA was able to control the distribution of some products generally regarded as devices by classifying these products as drugs, and therefore within FDA's domain. This approach did not achieve enough, however, largely due to the uncertainty surrounding which devices the courts would agree could legitimately be considered a drug. <sup>16</sup>

By the end of the decade, concerns mounted about the prevalence of injuries and deaths caused by medical devices.<sup>17</sup> Presidents Kennedy, Johnson, and Nixon recognized that giving FDA statutory authority to prevent the marketing of devices without adequate premarket testing could have prevented these deaths and injuries. Late in 1969, the Secretary of Health, Education, and Welfare convened a study group, chaired by Dr. Theodore Cooper, to evaluate the alternatives and devise the best approach to new, comprehensive device legislation. <sup>18</sup>

The Cooper Committee (as it has become known) found that 10,000 injuries, including 751 fatalities<sup>19</sup>, had occurred over a ten-year period. It concluded that the current system had become inadequate. Requiring FDA to prove that a product was adulterated or misbranded had

HR. REP. No. 94-853, at 7-8.

<sup>16</sup> *Id.* at 8-9.

Key examples of legitimate devices marketed without adequate testing include the Dalkon Shield intrauterine device, which was introduced in November of 1970 and by mid-1975, had been linked to 16 deaths and 25 miscarriages; faulty heart pacemakers, requiring recalls of 23,000 units; and implanted intraocular lenses that caused serious vision impairment, causing five patients to lose an eye. HR. REP. No. 94-853, at 8.

<sup>18</sup>

**H.R. REP.** No. 94-853, at 8-9.

<sup>19</sup> More specifically, the Committee found that 512 deaths and 300 injuries were caused by heart

valves; 89 deaths and 186 injuries by pacemakers; and ten deaths and 8,000 injuries from intrauterine devices. HR. REP. No. 94-853, at 8.

become increasingly difficult as technology grew more complex, and limiting the agency to ex post enforcement measures increased the amount of time the dangerous products remained on the market, thus increasing the harm suffered by the public. In its 1970 report, the Committee proposed a balanced regulatory system that would protect the public and give health care professionals more confidence in the devices they use or prescribe, without stifling the development of medical technology. To minimize unnecessary intervention, the Committee recommended a three-tier categorization of devices that would establish different levels of agency oversight for different types of devices.<sup>20</sup>

In 1976, Congress enacted the Medical Device Amendments of 1976<sup>21</sup>, adopting the regulatory system suggested by the Cooper Committee. As provided by this statute, FDA was to classify all medical devices as fitting into one of three categories. Class I devices are items for which general controls are sufficient to ensure safety and effectiveness<sup>22</sup>; class II devices are those for which performance standards must be established in order to guarantee safety and

**23**

effectiveness ; and class **III** devices are those for which premarket approval is necessary to

provide assurance of safety and effectiveness.<sup>24</sup> A device is deemed as class **III** when insufficient information exists to assure its safety through either the class I or class II procedures<sup>25</sup> and the device is used in supporting or sustaining human life or is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.<sup>26</sup> In

**20**

HR. REP. NO. 94-853, at 10-12.

**21** P L 94-295, 90 Stat. 539 (1976), codified at 21. U.S.C. §§ 351, 352, 360, 360c-360l.

**22**

21 U S C § 360c(a)(1)(A).

**23**

21 U S C § 360c(a)(1)(B).

**24**

21 U S C § 360c(a)(1)(C).

**25**

21 U S C § 360c(a)(1)(C)(i).

**26**

21 U S C § 360c(a)(1)(C)(ii).

addition, any device that had been on the market before the amendment was enacted, and is implanted into the human body, is presumptively class III unless the reviewing panel can substantiate a recommendation that premarket approval is not necessary in order to ensure safety and effectiveness.<sup>27</sup>

**B. Breast Implant Regulation from 1976-1992**

After the Medical Device Amendments were passed in 1976, the FDA Panel on General and Plastic Surgery Devices recommended that silicone breast implants be classified as a class II device on July 23, 1976.<sup>28</sup> Two years later, the Panel met and again recommended class II certification for silicone implants, with a high priority for FDA to implement performance standards. Then, in January of 1982, as part of a proposal to classify 55 general and plastic surgery devices, FDA proposed that this type of implant be classified as a class III device. FDA's decision not to follow the Panel's advice was based both on the statutory mandate to classify devices to be implanted in the body as category III, as well as the agency's assessment that insufficient information existed to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. At that time, FDA was primarily concerned direct, local complications, yet also indicated that long-term toxic effects might present an unreasonable risk.<sup>29</sup>

The Panel met again in January of 1983 to review and consider FDA's comments and unanimously recommended a class III category for the implants. The panel also recommended

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21 U.S.C. § 360c(c)(2)(C).

**28** See 53 Fed. Reg. 23856, 23862 (1988) (codified at 21 C.F.R. pt. 878.3540) (proposed June 24, 1988).

**29**

47 Fed. Reg. 23856 (1982) (codified at 21 C F R Pt 878 3540 ) (proposed Jan. 19, 1982).

researching the effects of silicone migration, and in February of 1994, FDA, in conjunction with the National Center for Toxicological Research, initiated a study in animals to examine this question.<sup>30</sup>

In early 1987, Dow Corning learned of results of a study in which rats that were implanted with a formulation of Dow Corning silicone gel showed an increased incidence of cancerous tumors at the implant site. Dow's expert panel evaluated the risks and concluded that there was no indication of risk to human health; however, the company decided to share the information with FDA and voluntarily submitted this study in August of that year.<sup>31</sup>

In June of 1988, FDA issued final device classifications, with silicone breast implants to be class III, again noting that insufficient information existed to establish performance standards that would provide reasonable assurance of safety and effectiveness of the devices.<sup>32</sup> Later that year, FDA issued a statement indicating that a patient warning should be developed for inclusion with the implants. This decision followed an FDA study identifying high priority devices.<sup>33</sup> Then, in October, FDA announced that the class III status would be discussed at an upcoming meeting of the advisory panel, at which the Dow data submitted in August 1987 would also be reviewed)<sup>4</sup>

In November of 1988, Health Research Group (ITRG), a consumer protection group focusing on health issues, became involved in the issue, releasing internal FDA and Dow

**30** *Silicone Teratology Study in Animals Underway*, M-D-D-I Reports, The Gray Sheet (Jul. 23, 1984).

**31** See *Teich v. FDA*, 751 F. Supp. 243, 246 (D.D.C. 1990)

**32**

21 C.F.R. Pt. 878.3540 (1997)

*~ Mammary prosthesis: patient inserts explaining risks needed, FDA study recommends*, M-DD-I Reports, The Gray Sheet (Aug. 15, 1988).

<sup>34</sup> *Mammary implants Class III status is subject of upcoming FDA advisory panel meeting*, M-DD-I Reports, The Gray Sheet (Oct. 17, 1988).

memoranda regarding the Dow studies indicating that mice injected with silicone had developed cancer: Later that month, the Panel met again, and at this time, heard HIRG's allegations about Dow Corning's data on cancer in mice)<sup>6</sup> The Panel concluded that the implants should remain on the market, yet recommended that further research be undertaken. Specifically, the Panel suggested that from that date until 1990, FDA and the American Society of Plastic and Reconstructive Surgeons (ASPRS) conduct a review of the existing national and international registries of implants to gather long-term data on known clinical and preclinical risks related to implants, including carcinogenesis and teratogenesis and immune disorders. The Panel also recommended studying the manufacturers' complaint files.<sup>37</sup>

At the November panel meeting, the assembled experts sought to review Dow Corning data on injectable silicone products, which had been submitted to FDA in connection with a new drug application submitted before the 1976 Amendments were enacted. FDA was unable to locate these studies, however, so the panel requested new copies of the information, as well as consumer complaint files, from Dow Corning. In January of 1989, Dow Corning re-submitted these studies, as well as later studies and a summary of its consumer complaint files.<sup>38</sup>

*~ Silicone gel breast implants should be banned, Health Research Group tells FDA, M-D-D-I*

Reports, The Gray Sheet (Nov. 14, 1988).

*'6 Breast implants: FDA is surveying manufacturers complaint files, databases, M-D-D-I*

Reports, The Gray Sheet (Nov. 28, 1988).

*~ See 55 Fed. Reg. 20568, 20570 (1990) (codified at 21 C.F.R. Pt. 878) (proposed May 17, 1990)*

**38**

Teich, 751 F. Supp at 246. Shortly after Dow Corning submitted this data to FDA, HRG filed a Freedom of Information Act request to gain access to this material, but FDA refused to release the data. *Industry & Washington Memos*, M-D-D-I Reports, The Gray Sheet (Feb. 20, 1989). The matter eventually was resolved through a suit in federal court, with a district court judge ruling that the manufacturers' study data and customer complaint files were subject to disclosure under FOJA. Teich, 751 F. Supp. at 255.

FDA moved to initiate proceedings to require premarket approval (PMA) applications for 31 devices assigned high priority, including silicone implants, in early January of 1989.<sup>39</sup> At this stage, the agency filed a notice of intent to initiate proceedings.<sup>40</sup> The proposed rule, however, was not announced until May 1990, at which time FDA announced the proposed requirements for PMAs for implants. In this proposal, FDA indicated that it sought clinical data, including retrospective epidemiological and prospective clinical studies to assess the potential of cancer and other long-term complications associated with silicone implants. According to the original timetable set by FDA, interested parties had a 60-day period for comments, and the tentative deadline for the submission of PMAs was set for December 31 of 1990, after which the devices could no longer be marketed without having FDA approval.<sup>41</sup> Many delays, however, prevented this plan from being implemented as scheduled.

The comment period had been slated to close in mid-July, but was extended for an additional two months.<sup>42</sup> By the comment period's closure on September 14, FDA had received 2,670 comments to evaluate.<sup>43</sup> In December, the House of Representatives Government Operations Committee held a hearing to investigate the progress on this issue, at which time FDA indicated that the final rule calling for PMAs would be issued in March 1991, following a national conference being convened in February.<sup>44</sup>

<sup>39</sup> 54 Fed. Reg. 550 (1989) (notice published Jan. 6, 1989).

<sup>40</sup> *Breast implant call for PMAs has been drafted by FDA device center*, M-D-D-I Reports, The Gray Sheet (Jan. 30, 1989).

<sup>41</sup> (codified 55 Fed. Reg. 20568, 20570 (1990) at 21 C F R pt. 878) (proposed May 17, 1990).

<sup>42</sup> 55 Fed. Reg. 29223 (1990) (codified at 21 C F R Pt 878) (proposed Jul. 18, 1990).

<sup>43</sup> *Id.*

<sup>44</sup> *Silicone Gel-filled implants: final call for PMAs will issue in March 1991*, M-D-D-I Reports, The Gray Sheet (Dec. 24, 1990).

Ultimately, the final rule requiring PMAs was issued on April 10, 1991, requiring manufacturers to submit PMAs by July 9. If PMAs were not submitted by that time, commercial distribution was to cease.<sup>45</sup> In September, FDA announced that although it was still reviewing the data submitted by four manufacturers—Bioplasty, Inc., McGhan Medical Corp. Mentor Corp. and Dow Corning<sup>46</sup>—it had identified significant deficiencies in the PMAs for the silicone implants. Until the final decision was made regarding the PMAs, FDA would regard any device as misbranded that did not provide adequate written information to patients on the potential risks associated with silicone implants. The agency issued a sample patient warning notice, which focused on the risks of local complications and also raised the possibility that silicone migration could cause cancer or autoimmune diseases.<sup>47</sup>

Although FDA was dissatisfied with the data contained in the four PMAs, the advisory panel met in mid-November to evaluate the applications and hear testimony from physicians, patients, advocacy groups, and others. The panel issued a number of conclusions and recommendations. First, the panel determined that the available data did not provide reasonable assurance of the safety and effectiveness of these devices and agreed with FDA's scientists that the clinical data provided by the manufacturers were not adequate to alleviate the safety concerns. Because the panel also decided that the breast implants served a public health need, it voted unanimously to recommend that FDA keep the device on market while further data were

56 Fed. Reg. 14620 (1991).

<sup>46</sup> Citizen Petition on behalf of medical professional and cancer patient advocacy groups to FDA,

Sept. 19, 1996, at 8 n.7.

56 Fed. Reg. 49098 (1991) (notice published Sept. 26, 1991).

collected.<sup>48</sup> The panel also suggested that FDA establish a patient registry to enable manufacturers to track patients and outcomes.<sup>49</sup>

After the November 1991 panel meeting, FDA received information about data that had not been presented to the panel. The data indicated that one manufacturer had not followed satisfactory quality control procedures to prevent safety problems, had not undertaken adequate animal studies before the products were promoted for human use, and did not act on evidence indicating problems that had been acquired years earlier. It was also at this time that FDA became aware of the possible association between implants and connective tissue diseases.<sup>50</sup>

In light of this new evidence, On January 6, 1992, FDA Commissioner David Kessler decided to request a voluntary moratorium on the distribution of implants until the advisory panel could evaluate the newly-acquired information.<sup>51</sup> After Kessler announced the moratorium, further information was revealed, regarding the silent rupture problem. **52**

The panel reconvened in mid-February of 1992 to hear testimony from doctors, companies and consumers. At this stage, the discussions focused on the incidence and hazards from ruptures and gel bleed, the possible link to autoimmune disease, and the industry's record on testing, reporting and marketing of these implants over the preceding 30 years. After these hearing, the panel issued four recommendations, most notably altering its stance on the continuing availability of silicone gel implants on the market. The panel now recommended that further use of these

**48** Panel Issues Breast Implant Recommendations, Nov. 15, 1991 (FDA talking paper T9 1-72); Kessler statement, *supra* note 3.

**49**

Kessler statement, *supra* note 3. In March 1992, FDA proposed a regulation to establish a

device tracking requirement for certain categories of devices, including breast implants. 57 Fed. Reg. 10702 (1992) (codified at 21 C.F.R. pt. 821) (proposed March 27, 1992).

Kessler statement, *supra* note 3.

**51**

57 Fed. Reg. 3634, 3635 (1992) (notice published Jan. 30, 1992).

**52**

Kessler statement, *supra* note 3.



implants be restricted to use by women participating in scientific protocols, with unrestricted access for women needing breast reconstruction but limiting the number of women seeking augmentation to that needed to study the safety of implants for this type of patient. Further, the moratorium was to continue until FDA decided how to proceed given these new recommendations. The panel also suggested that epidemiological studies be conducted to assess the risk of autoimmune disease, yet concluded that no causal link had been established thus far. In addition, the panel recommended that women with implants be checked regularly to ensure that their implants had not ruptured, and that the manufacturers must provide adequate preclinical data on the chemical and physical properties of the implants.<sup>5</sup>

Two months later, FDA's Commissioner adopted the panel's recommendation to limit the availability of implants. For reconstructive purposes, the manufacturers' PMAs were left open with studies to continue for additional data collection. For augmentation purposes, however, the PMAs were denied and manufacturers were then required to submit Investigation Device Exemptions to conduct FDA-approved research studies. The moratorium on distribution ended with the agency's actions on the PMAs.<sup>54</sup>

#### C. Post-1992 Ban

Four months after FDA's PMA decision were announced, the agency approved clinical studies of silicone implants to be conducted by Mentor Corp., which limited participation to

~ *Id.*; FDA Panel Makes Breast Implant Recommendations, Feb. 20, 1992 (FDA press release T92-9).

Kessler statement, *supra* note 3.

women needing reconstructive surgery or implant replacements.<sup>55</sup> Meanwhile, private researchers continued to explore the possible risks of silicone implant, particularly autoimmune diseases. In March 1993, FDA reported the results of animal studies showing that silicone gel can act as antibody adjuvant. As a result, the agency amended its patient information regulations, requiring manufacturers to update information about the possible connection in the informed consent documents used to apprise women undergoing implant surgery of the possible risks.<sup>56</sup> On other fronts, however, several epidemiological studies were published indicating that no link could be established between silicone implants and autoimmune diseases.<sup>57</sup> An April 1996 review of the literature regarding the safety of breast implants revealed that no study has indicated that the rate of well-defined connective tissue disease or breast cancer has greatly increased in women with silicone breast implants, but no studies have ruled out a moderate increase. In addition, there are not yet adequate studies assessing the frequency of local complications, particularly rupture and capsular contracture.<sup>58</sup>

FDA Approves Clinical Studies of Silicone Breast Implants, Aug. 3, 1992 (talking paper T92-35).

**56**

Immunology Studies on Silicone Gel, Mar. 22, 1993 (FDA talking paper T93-15).

~ See, e.g., D. Schottenfeld, et al., *The Design of a Population-Based Case-Control Study of*

*Systemic Sclerosis (Scleroderma,): Commentary on the University of Michigan Study*, 48 J. CLIN.

EPIDEMIOL. 583 (April 1995); SE. Gabriel, et al., *Risk of Connective-Tissue Diseases and Other*

*Disorders after Breast Implantation*, 330 NEW ENG. J. MED. 1697 (June 16, 1994); **H.J. Englert**,

et al., *Scleroderma and Augmentation Mammoplasty –A Causal Relationship?*, 24 AUST. N.Z.

J. MID. 74 (February 1994); M. Schusterman, et al., *Incidence of Autoimmune Disease in*

*Patients After Breast Reconstruction with Silicone Gel Implants Versus Autogenous Tissue: A*

*Preliminary Report*, 31 ANN. PLAST. SURG. 1 (July 1993); **CE. Dugowson**, et al., *Silicone Breast*

*Implants and Risk for Rheumatoid Arthritis*, 35 ARTI-RITIS RHEUM. (SUM.), ABSTRACT 192:S 66

(September 1992).

**58** *The search of medical literature on the safety of breast implants adapted from the Annals of*

*Internal Medicine, April 15, 1996*, HEALTHFACTS, (Center for Med. Consumers, Inc.), May

1996, at 2.

#### IV. Analysis of FDA Actions

##### A. Timing of Efforts

###### 1. *Moving Too Slowly*

FDA was criticized, particularly by members of Congress, for its delay in acting to regulate silicone breast implants.<sup>59</sup> Although it seems that little occurred between the late 1970s and early 1980s and 1991<sup>60</sup> when FDA issued its final rule requiring the submission of PMA applications, when one looks at the internal processes within the agency, this charge loses much of its weight. It seems that no action was taken between 1983 and 1988, but once the device was provisionally categorized as a class III device in the middle of 1988, the agency made relatively steady progress, particularly in light of the fact that collecting adequate data on safety and effectiveness is by necessity a process that requires several years.

###### 2. *Moving Too Quickly*

From the other side, FDA has been attacked for moving too rapidly to limit market availability of the implants while the data were not conclusive.<sup>61</sup> The coalition of cancer patient advocacy groups and medical professionals who have petitioned the agency to reconsider its policy have argued that under the Safe Medical Devices Act of 1990<sup>62</sup>, which amended the

<sup>59</sup> *See, e.g.*, REPORT ON TI-IF ACTIVITY OF THE COMMITTEE ON ENERGY AND COMMERCE, H.R.

REP No 102-1096, 102nd Cong., 2nd Sess.(1992), *available in* WESTLAW, 1992 WL 405925

(Leg. Hist.).

<sup>60</sup>

In 1971, FDA compiled an inventory of potential devices to be regulated. This list included

approximately 8,000 separate devices. H.R. REP. No. 94-853, at 11. Given the immense scope of the regulatory burden that had been added to the agency's domain, it is understandable that FDA could not act quickly for each of these items.

<sup>61</sup> Citizen Petition, *supra* note 46, at 7.

<sup>62</sup> Safe Medical Devices Act, Pub. L. 101-629, 104 Stat. 4511(1990), 21 U.S.C. §§ 301 note,

321, 333, 351, 353, 360, 360c-j, 3601, 3SOgg-hh, 360ii-ss, 42 U.S.C. §§ 263b-n.

Federal Food, Drug, and Cosmetic Act, the agency had until December 1, 1995, to reclassify the implants.<sup>63</sup> This argument seems to ignore both the development of the agency's policy as well as the provisions of the statute.

As implantable devices, the silicone prostheses were presumptively categorized as class III, and could only be reclassified into a lower category with evidence that the more stringent requirements were not necessary.<sup>64</sup> Given the state of information regarding the safety of the breast implants, it is clear that FDA had no choice but to classify the implants as class III. In addition, the agency had already reviewed the class III status in the middle of 1988—over a year before the House Subcommittee had held the hearings that led to the passage of the 1990 Amendments.<sup>65</sup> In sum, given that the classification of the silicone implants had already been reviewed, it is unclear that the provisions of the 1990 Amendments were applicable at all.

Even if the 1990 Amendments were intended to cover those class III devices that had previously been reviewed, Congress enacted the 1990 amendments to streamline the regulatory

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process, *not* to provide a basis for delaying a PMA process that had already begun. Having classified silicone implants as class III in June 1988, the agency could have required PMA

application submissions from the manufacturers as early as December 31, 1990.<sup>67</sup> Although it did not issue the final rule until April of 1991 and therefore moved the final PMA application

**63** Citizen Petition, *supra* note 46, at 7.

**64**

21 U.S.C. § 360c(c)(2)(C).

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REPORT ON THE ACTIVITY OF THE COMM. ON ENERGY AND COMMERCE, **HR.** REP. No. 101-398, 101st Cong., 2nd Sess (1990), *available in* WESTLAW, 1990 WL 259119 (Leg. Hist.).

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HOUSE COMM. ON ENERGY AND COMMERCE, REPORT ON **P.L.** 101-629, SAFE MEDICAL DEVICES ACT OF 1990, **HR.** REP. No. 101-808, 101st Cong., 2nd Sess. (1990), *reprinted in*

U.S.C.C.A.N. 6305, *available in* WESTLAW, 1990 WL 200530 (Leg. Hist.).

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In fact, this date was the preliminary deadline that FDA had established when it issued the

proposed rule for the PMA applications in May of 1990. 55 Fed. Reg. 20568 (1990) (codified at 21 **C.F.R.** pt. 878) (proposed May 17, 1990).

submission deadline to July, 1991<sup>68</sup>, FDA would have been following Congressional mandate by proceeding as quickly as possible, not by revisiting the issue of class III categorization.

B. Decision-making Process

1. Factors Affecting Timing

Critics have charged that FDA's actions were stimulated by improper motives. According to this view, rather than moving forward with the regulatory process because the agency had determined—on some sort of rational basis—that the risks and benefits silicone implants should be scrutinized more closely, FDA only paid attention to the problem when the litigation surrounding implants had increased and the media had drawn attention the issue, creating public pressure for

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action. Essentially, the charge is that the agency was influenced by politics and other extra-scientific concerns instead of being directed by science.

Such a purist vision of how FDA ought to operate does not account for the administrative system operating in the United States. While an administrative agency ought to operate differently than a legislature in that professional expertise ought to ground the organization's decisions, an agency cannot be immune to public opinion regarding the agency's policies. Even if one's notions of democracy would be untroubled by a system in which government professionals are entirely unaffected by the ideas of the populace, it is naive to think that this degree of insularity is possible in the United States. An appointed agency chief is ultimately accountable to the President, who *is* expected to consider the political implications of a particular decision. This fact in itself makes politics an element an administrator must consider. In addition, an intelligent policy-maker

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21 C.F.R. Pt. 878.3540 (1997).

*e.g.*, ANGELL, *supra* note 1, at 25.

understands that a certain degree of overlap between what the public perceives is a wise policy and what truly is a wise policy is necessary in order for a program to be implemented.<sup>70</sup> If the public perceives a new a policy as unwise, the government leader stands little chance of achieving her goals, no matter how sound the policy may be. Thus, an agency executive must be aware of the prevailing views among the electorate, so that her policies are not thwarted by legislative bodies that are empowered to limit the agency's discretion.

One must also acknowledge that the inactivity of an agency can also be the result of political choices. As some commentators have pointed out, under the Reagan administration, the lax regulatory stance gave FDA officials little incentive to promulgate new regulations.<sup>71</sup> If this is the case, the changes in the political climate and the pressures placed on Congress by panicky constituents that pushed the agency to act more quickly can be viewed as a necessary corrective for the politically motivated choices of the previous administration.

Leaving aside the questions of the proper role of politics in agency decision-making, it remains unclear what influence extra-scientific factors did have. In terms of FDA's pace in acting on the silicone implant issue, a variety of factors impacted the progress of the agency's activities. Although the early lawsuits probably contributed to the release of new information regarding potential hazards of the device, the spurt of litigation did not occur until after the 1992

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moratorium ,and well after FDA had intensified its scrutiny of silicone implants, making it

**70** Philip B. Heymann, Relations Between Politics and Policy (Sept. 14, 1996) (course materials from Problems of Law Enforcement, Harvard Law School, fall semester, 1996) (on file with author).

**71** **HR. REP.** No. 102-1096.

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Dow Corning reported an increase in lawsuits from about 200 at the end of 1991 to 10,000 by

the end of 1992. ANGELL, *supra* note 1, at 69 (citing interview with Bane S. Carmichael, Dow Corning corporate vice-president, TJFR HEALTH NEWS REPORTER (June 1995)).

impossible that the fallout from the lawsuits spurred the agency to act. The trickle of anecdotal medical evidence regarding possible immune system problems, as well as the data on cancer submitted by Dow in 1987, also contributed to FDA's decision that the time for an evaluation had arrived.

FDA undoubtedly was driven by appropriate scientific concerns, as well as constraints on administrative resources<sup>74</sup>, but it is also accurate to conclude that politics did play some role in pressing FDA for decisive action on silicone breast implants. The agency was criticized by the House of Representatives' Committee on Government Operations late in 1990, with the subcommittee concluding that FDA should respond more quickly and strongly in requiring that adequate information be collected to assess the risks of silicone implants.<sup>75</sup>

Nonetheless, Congressional inquiries of this sort are not inherently an inappropriate mechanism for affecting policy. Congress can delegate certain powers to administrative agencies~ yet in order to maintain the balance of powers mandated by the Constitution, these agencies remain accountable to Congress.<sup>76</sup> If Congressional pressure for agency action results from one powerful member flexing her muscles on behalf of a particular interest group or a powerful constituent, one's objections to the interference with agency policy would be justified. When

~ For example, the major case that revealed the risk of connective tissue diseases was not decided until late in 1991~after the PMAs had been submitted and found inadequate. *See Hopkins v. Dow Corning Corp.*, 1992 WL 176560 (ND. Cal. 1992).

One should remember that the pressure to address curative and preventive measures for AIDS had intensified during the late 1980s, a period of increasing burdens and decreasing resources for **FDA**. *See* Larry Thompson, *FDA Faces Many Other Problems, Too*, WASH. POST, Aug. 22, 1989. It is thus possible that when this issue became a top priority, FDA attention, if not resources, was diverted.

~ **HR.** REP. No. 101-1006.

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For a discussion of the doctrine and mechanisms of legislative delegation to administrative

agencies, *see* PETER L. STRAUSS ET AL., GELLHORN AND BYSE'S ADMINISTRATIVE LAW ch. 2, § I (9th ed. 1995).

Congress probes into agency inaction on a subject that the agency's own staff and advisory panel have deemed important, however, this type of oversight is an example of the way Congress can see that its mandate is being fulfilled. Of course, most inquiries into agency policy will not fall neatly into one category or the other, and people may disagree as to whether a particular instance demonstrates legitimate Congressional supervision or strong-arming to please special interests. As a general matter, however, it is both unavoidable and desirable that politics—through legislative checks on administrative agencies—will impact agency decisions.



2. *Factors Affecting Outcome*

Critics of FDA's handling of the silicone implant issue have also claimed that the actual decision reached was tainted by both improper evidence and the biases or lack of qualifications of panel members. Several commentators have noted that at the February 1992 hearings, the data indicating a connection between silicone breast implants and connective tissue diseases were not merely insufficient to establish such a connection, but were also not the type of data that should be used to conclude that a particular risk factor—i.e., silicone breast implants—is connected to the incidence of a particular symptom or disease.<sup>77</sup>

Epidemiological data is the appropriate basis for judgments of this sort, yet no solid epidemiological studies had been completed by February of 1992. Instead, the panel members heard only anecdotal evidence of doctors who had observed a connection between women with breast implants and connective tissue diseases. As has been noted by both doctors analyzing the breast implant saga<sup>78</sup> and the members of Congress who drafted the device amendment<sup>79</sup>, this type of anecdotal evidence should not be used as the basis of conclusions regarding the level of a particular risk. The unreliability of anecdotes is well-illustrated by the breast implant case. The

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JAMA, *supra* note 8; *Hearings on Silicone Implants Before the Subcomm. on Human*

*Resources and Intergovernmental Relations of the House Comm. on Government Reform and*

*Oversight*, 104th Cong., 1st Sess. (1991) (statement of John S. Sargent, M.D., Chairman,

Department of Medicine, St. Thomas Hospital, Professor of Medicine, Vanderbilt Univ. School of Medicine), *available in* WESTLAW, 1995 WL 460638 (F.D.C.H.) [hereinafter Sargent

statement]; *Hearings on Silicone Implants Before the Subcomm. on Human Resources and*

*Intergovernmental Relations of the House Comm. on Government Reform and Oversight*, 104th

Cong., 1st Sess.(1991) (statement of Elizabeth B. Connell, M.D, Professor, Dept. of Gynecology

and Obstetrics, Emory Univ. School of Medicine), *available in* WESTLAW, 1995 WL 457360

(F. D.C.H.) [hereinafter Connell statement].

**78** JAMA, *supra* note 877; Sargent statement, *supra* note 77; Connell statement, *supra* note 77;

ANGELL, *supra* note 169, at 105.

**HR. REP.** No. 94-853, at 17.

awareness that the connection might exist, which grew dramatically after the 1992 ban, increased the likelihood that women who are ill would come to attention. Further, certain doctors gained a reputation for believing that the link was real and thus became a magnet for women with connective tissue diseases who also had breast implants, and the resulting reporting bias is likely to have influenced the data significantly. <sup>80</sup> If the weakness of anecdotal evidence as a general matter was sufficiently clear to the non-scientist legislators that drafted the device amendment, Kessler and his staff should have been able to distinguish between information that merely signaled an area for further research from data that genuinely indicated a correlation between the risk factor and the disease.

One of the physicians who served on the February 1992 panel, Dr. John Sargent, also has pointed out that the group assembled was not qualified to make the assessments that FDA sought. While the panelists may have been experts in their particular fields, the cumulative expertise was nonetheless inadequate for evaluating the connection between connective tissue diseases and silicone breast implants. The panel contained only two rheumatologists, the specialists who best understand these illnesses, and the only epidemiologist and the only immunologist on the panel were not familiar with the diagnostic challenges presented by these complex rheumatic diseases.<sup>81</sup> The panel's suitability was further compromised by the fact that some members had stated, on record, their views opposing implants, with this opposition often having little or nothing to do with connective tissue diseases.<sup>82</sup> In addition, before the November 1991 panel meetings, FDA revoked the voting privileges of five panelists when opposition arose to the participation of three

<sup>80</sup> ANGELL, *supra* note 1, at 105; Sargent statement, *supra* note 77.

<sup>81</sup> Sargent statement, *supra* note 77.

physicians with strong ties to plastic surgery trade associations and two doctors who had testified

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or consulted on behalf of plaintiffs involved in implant litigation. The weaknesses of both panels illustrate that FDA was not sufficiently careful in its selection of panelists.

C. Kessler's Controversial Decisions

David Kessler has been criticized for his handling of the implant situation in 1992. The

voluntary moratorium declared on January 6, together with the eventual ban announced in April,

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drew tremendous media attention consequently fed the growing panic among women

who already had or were considering silicone implants,<sup>85</sup> and caused a surge in the litigation against implant manufacturers.<sup>86</sup> In addition, the policy of restricting access for implants for women seeking augmentation has been viewed as both unfair and irrational. Although the basic conclusion that the manufacturers had not met their burden of proving that the devices were safe has not been questioned<sup>87</sup>, the policies based on this evaluation were not chosen wisely.

*1. The Voluntary Moratorium and the Ensuing Ban*

Even if Kessler was correct in concluding that the data acquired late in 1991 were significant to warrant a change in FDA policy, declaring a moratorium on the use of silicone implants was unnecessarily drastic given the nature of the new information. The documents

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Citizen Petition, *supra* note 46, at 8 n. 8 (citing *Breast Implant Foe Loses Vote on Safety Panel*,

Boston Globe, Feb. 13, 1992, at A3).

84 Connell statement, *supra* note 77.

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86 See *supra* note 72 and accompanying text; Jack C. Fisher, *The Silicone Controversy—When*

*Will Science Prevail?*, 326 N. ENGL. J. MED. 1696-1698 (1992).

87 ANGELL, *supra* note 1, at 21.

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indicated that manufacturers had not followed adequate quality control measures and had not conducted thorough preclinical tests, and that some physicians reported an association between connective tissue disorders and breast implants, a connection that immunologists confirmed was the subject of concern.<sup>88</sup> Kessler was right to be convinced that consumers might [have been] at greater risk than [the agency] had anticipated earlier,<sup>89</sup> but given the absence of any epidemiological data supporting the suspicions regarding connective tissue diseases, and the fact that the information did not point to the possibility of immediately life-threatening risks, Kessler's response was an overreaction.<sup>90</sup>

Dr. Elizabeth Connell, chair of the advisory panel in November 1991 and in February 1992, has expressed concern that [b]ecause of the intense and often misleading media coverage of this issue, particularly after the moratorium, we have seen fear, panic, and incredible levels of distress..., among those women who have been led to believe that they were wearing very dangerous devices and were at risk for serious health consequences.<sup>91</sup> While Kessler cannot have been expected to predict the exact extent of the media and public reaction, in light of the media scrutiny that had already intensified by that time, Kessler should have foreseen that such an unprecedented and extreme step would have a major impact on public perception regarding the safety of implants. At the very least, he should have considered whether other measures, such as issuing a statement to surgeons with updated information to be shared with patients, would have

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Kessler statement, *supra* note 3.

**89** *Id*

**90** Although FDA was statutorily directed to respond to the **PMA** applications by January 6, the

statute also gives the Secretary the authority to extend the period in which action is to be taken if he finds the continued availability is necessary for the public health. 21 U.S.C. §§ 360e(d)(1)(A), 360e(d)(1)(B)(i).

**91** Connell statement, *supra* note 77.

provided sufficient protection until the advisory panel could reconvene the following month to

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fully assess the new evidence.

Because the ban, together with the attendant media coverage, has exaggerated the risk of

implants in the minds of the public, FDA has the duty to undertake the task of updating the public. Doctors have called upon the agency to issue a public statement regarding the consensus that has developed in the medical community indicating that the epidemiological evidence now available indicates little, if any, connection between silicone implants and connective tissue diseases.<sup>93</sup>

The January and April actions may also have had a broader impact on FDA's ability to influence public opinion. By wielding the powerful tool of a moratorium to control a risk that was relatively small on the scale of potential public health hazards, Kessler may have weakened the impact that a future moratorium might have in the event of a more serious threat to public safety, and eroded the public's confidence in the agency's competence in risk evaluation. On a more general note, by exaggerating the risk of implants, Kessler has exacerbated the problems Americans face in comparing relative risks accurately.<sup>94</sup>

2. *Final Decision Allowing Different Access/or Reconstruction than Augmentation*

Perhaps the most controversial aspect of FDA's 1992 actions was the decision to draw a distinction between the degree of access to be afforded women seeking reconstructive surgery, and that granted to women seeking augmentation. Physicians and consumer groups alike viewed

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We cannot know what choices were in Kessler's mind, yet in his explanation of his policies, he

has not indicated that he considered, but ruled out, a less drastic measure.

~ **Connell statement**, *supra* note 77.

~ See ANGELL, *supra* note 1, at 175-176 for a discussion of Americans' poor track record in evaluating health risks.

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this as an inappropriate differentiation, which deprived American women of their ability to choose the risks they feel are worth taking.<sup>95</sup>

Kessler has offered two justifications for drawing the distinction between the categories of women seeking implants. First, he argues that the benefits of reconstructive surgery are higher than those received by women seeking augmentation. He acknowledges that the needs of both groups are cosmetic, but ultimately concludes that the needs of the patient who desires

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reconstructive surgery differ from those of the patient who desires augmentation.

fact that insurance companies generally pay for reconstructive surgery—which he categorizes as an integral part of cancer treatment, while they will not reimburse patients for augmentation, as evidence that there is a societal consensus that the former is more important. Kessler’s second defense is that women seeking augmentation face an additional risk that women having undergone mastectomies do not, i.e., the risk that breast cancer will be more difficult to detect. He has said that *this* is the reason why the risk-benefit analysis yields different results for the two groups of

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women.

These arguments are weak for several reasons. First, Kessler’s conclusion that [i]t makes

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little sense for the FDA to consider breast augmentation of equivalent importance with reconstructive surgery is essentially a value judgment, as his discussion of social norms reveals.

~ See *California Society of Plastic Surgeons Group Says FDA Sets Doubtful Standard on Silicone*

*Gel Breast Implants*, *CANCER WEEKLY*, May 4, 1992; *JAMA*, *supra* note 8; *ANGELL*, *supra* note

1, at 63.

<sup>96</sup> David A. Kessler, *The Basis of the FDA’s Decision On Breast Implants (Special Report)*, 326

N. *ENG. J. MED.* 1713-15 (1992). <sup>97</sup> *Id*

<sup>98</sup> *Id*

*Id*

He then refers to the policies of insurance companies as if the decisions regarding reimbursement or compensation contain no element of value judgment. For example, the fact that some insurance plans will reimburse women for contraception, while others will not, reflects differences in values among those making the choices as to which items will be covered.

Because Kessler's policy is based on a subjective evaluation of the benefits of breast implants, it should not be the basis for FDA policy. One might personally feel that reconstructive surgery comes *closer* to being a necessity than does augmentation, much as one might agree that plastic surgery to correct scarring from an accident is more necessary than the standard facelift (and the reimbursement policies of insurance companies may support this distinction as well), yet one also must acknowledge that this calibration is in fact a value judgment. While it is true that by establishing FDA, we have chosen to surrender a degree of our autonomy as consumers, an imprecise criterion such as psychological benefit is an insufficiently objective basis for limiting the choices of women seeking augmentation.

Kessler denies that he is making a value judgment, and asserts that the policy distinguishes between the categories of patients based on the increased risk faced by women seeking augmentation, not based on the lesser benefit.<sup>99</sup> By shifting his emphasis to this reason for the distinction, Kessler implicitly acknowledges that the difference in benefits *is* a subjective evaluation. If the initial justification were not a value judgment, why did Kessler feel compelled to put forward the second rationale?

The differences in resistance levels between the two groups of women necessitate conducting clinical trials with both types of subjects, a fact that probably underlies the agency's

decision to allow women seeking augmentation to receive silicone implants on a limited basis. If two sets of trials were needed, however, it is unclear why the agency decided that only the women seeking reconstructive surgery should have unlimited access. With the ethical concerns surrounding the participation of women who have had cancer, restricting the participation of these women to the minimum number necessary to collect adequate data would seem to have been the best policy. Thus, it is hard to believe that the agency was not making a distinction between the two groups on the benefit side of the equation. Without valuing the benefit derived by the women having reconstructive surgery more highly, the sensible policy would have been to treat the two groups the same, because each faced a risk that the other did not. In fact, in light of the fact that approximately 80 percent of women who desire implants are patients undergoing augmentation<sup>100</sup> if either group was to have increased access, one could argue that it is the women wanting augmentation who should have been granted this advantage.

Even if Kessler's focus on the complications in detecting cancer in women with implants is not pretextual, there are reasons to question whether this decision is sound. Given the uncertainty surrounding the magnitude of the risk these women face<sup>101</sup>, Kessler has not articulated why the added risk is sufficient to tip the balance, particularly if the alleged increased benefit for women with reconstruction is *not* part of the calculus. In addition, with Kessler's genuine concern for protecting vulnerable patients, it is curious that he has not addressed the additional risk for autoimmune disease that women who have suffered from cancer may face.<sup>102</sup>

**100** FDA Calls for a Moratorium on the Use of Silicone Gel Breast Implants (FDA press release P92-i).

**101** Although there is some indication that implants interfere with effective breast cancer detection,

some authorities believe that women with implants are less at risk than those without because the women with implants are more conscientious about routine testing. JAMA, *supra* note 8.

**102** See Kessler, *supra* note 96.



## V. Conclusion

In the end, the decision to restrict availability of silicone breast implants was appropriate. **FDA has been** clearly directed by Congress to withhold approval for a medical devices that have not been proven safe and effective, and as of 1992, the implant manufacturers had failed to meet this burden. There were, however, problems in how FDA handled the matter, which can provide insight for improving the agency's performance. First, FDA should be more rigorous in screening data that is submitted to an advisory panel. If the agency is charging a panel with the task of making a decision on an item's safety, anecdotal evidence should not be accorded the same weight as epidemiological data.

Second, the agency should attempt to tailor the composition of its advisory panels more closely to the expertise required by the particular devices or drugs being evaluated. Even if there are general panels for most cases, when a product presents a particularly complicated question, the agency should find experts with specialized expertise to supplement or replace the standing members. While FDA attempted to follow this type of procedure by adding two rheumatologists to the February 1992 panel, the degree of specialization required was still not met. In addition, although the agency cannot be entirely free from external, political forces, more care is needed when selecting panel members, to minimize the risk of bias by the evaluators.

Third, FDA must recognize that part of its mandate involves educating the public, and to this end, it must be aware of the impact of its decisions on public perceptions. Not only does this obligate the agency to provide the latest information on the health and safety issues, but it also requires that the administrators assess the impact a policy decision will have when announced.

Thus, the affirmative duty to inform the public is coupled with a duty to refrain from conveying information in a manner that will unnecessarily cause panic. Additionally, when public opinion has already diverged from an accurate assessment of a certain risk, FDA should act to correct these misperceptions.

The last problem with FDA's decision, the distinction between women desiring reconstructive surgery from those seeking augmentation, illustrates the problems that arise if FDA allows subjective judgments to cloud the decision-making process. In the end, however, the line between subjective value-judgments and objective science is not clear. The agency attempts to find the appropriate balance between protecting public health and allowing consumers to make their own choices regarding risks, and some issues relating to values necessarily enter the equation. FDA chose poorly in this instance, yet if we are to have an agency that we entrust with protecting public health, we must acknowledge that some errors in one direction or the other will occur.